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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMERICAN REGENT, INC., *Plaintiff*, v. GLAND PHARMA LIMITED, *Defendant.*	Civil Action No. 2:24-cv-07756 (Filed Electronically)

AMENDED COMPLAINT FOR PATENT INFRINGEMENT TO GLAND PHARMA

Plaintiff American Regent, Inc. ("ARI" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendant Gland Pharma Limited ("Gland Pharma" or "Defendant") alleges as follows:

NATURE OF THIS ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, arising from Gland Pharma's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 219632 ("the ANDA") which contained a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certification") seeking approval to engage in the commercial manufacture, use, sale, and/or importation of generic versions of ARI's Tralement® (trace elements injection 4*, USP) in 1 mL single-dose vials and Multrys® (trace elements injection 4*, USP) in 1 mL single-dose vials drug products ("the ANDA Products") prior to the expiration of United States Patent Nos. 11,786,548 ("the '548 patent"), 11,975,022 ("the '022 patent"), 11,998,565 ("the '565 patent"), 12,150,956 ("the '956 patent"), and 12,150,957 ("the '957 patent") (collectively, the "Patents-in-Suit").

2. By email correspondence dated December 19, 2024, Gland consented to the filing of this Amended Complaint.

THE PARTIES

3. ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

4. On information and belief, Gland Pharma is a corporation organized and existing under the laws of India with its principal place of business at Survey No. 143-148, 150 & 151 Near Gandimaisamma 'X' Roads D.P. Pally, Dundigal Gandimaisamma Mandal MedchalMalkjgiri District, Hyderabad 500043, Telangana, India.

JURISDICTION AND VENUE

5. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. On information and belief, this Court has personal jurisdiction over Gland Pharma under the New Jersey state long arm statute and consistent with due process of law because Gland Pharma has extensive contacts with the State of New Jersey and regularly does business in this judicial district. Further, Gland Pharma plans to sell the ANDA Products in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

7. This Court has personal jurisdiction over Gland Pharma because Gland Pharma has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contact with the State of New Jersey. On information and belief, Gland Pharma regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Gland Pharma derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. On information and belief, Gland Pharma derives substantial revenue from selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

8. This Court has personal jurisdiction over Gland Pharma because, on information and belief, Gland Pharma derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

9. Upon information and belief, Gland Pharma is in the business of, among other things, the development, manufacturing, importation, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this judicial district. Gland Pharma's website states that Gland Pharma has "a global footprint across 60 countries, including the United States," with a "focus on complex injectables including NCE-1s, First-to-File products and 505(b)(2) filings."[1]

10. This Court has personal jurisdiction over Gland Pharma because, *inter alia*, Gland Pharma has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to ARI in New Jersey. Further, on information and belief, following the FDA's approval of the ANDA, Gland Pharma will make, use, import, sell, and/or offer for sale the ANDA Products in the United States, including in New Jersey, prior to the expiration of the Patents-in-Suit.

11. On information and belief, this Court also has personal jurisdiction over Gland Pharma because it has previously availed itself of the legal protections of the State of New Jersey by, among other things, not contesting jurisdiction in this judicial district, and pursuing counterclaims in this judicial district, including in at least *Merck Sharp & Dohme LLC v. Gland Pharma Limited*, No. 22-05461, ECF No. 12 (D.N.J. Mar. 6, 2023).

12. In the alternative, this Court has personal jurisdiction over Gland Pharma because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) ARI's claims arise under federal law; (b) Gland Pharma is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Gland Pharma has sufficient contacts with the United

[1] https://glandpharma.com/about (last accessed June 25, 2024).

States as a whole, including, but not limited to, preparing and submitting the ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Gland Pharma satisfies due process.

13. Venue is further proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

14. On information and belief, venue is proper in this judicial district under 28 U.S.C. § 1391(c)(3) because Gland Pharma is a foreign company not residing in any United States judicial district and may be sued in any judicial district.

BACKGROUND

15. ARI holds New Drug Application ("NDA") No. 209376 for Tralement® (trace elements injection 4*, USP) and Multrys® (trace elements injection 4*, USP), which were approved by the FDA on July 2, 2020 and which ARI manufactures and sells in this judicial district and throughout the United States.

16. Tralement® is the first and only FDA-approved multi-trace element injection product for patients weighing at least 10 kg. The FDA has approved both 1 mL and 5 mL forms of Tralement®; ARI markets a 1 mL Tralement® product.

17. Tralement® is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate, and selenious acid) indicated in adult and pediatric patients weighing at least 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

18. Multrys® is the first and only FDA-approved multi-trace element injection product for neonatal and pediatric patients weighing less than 10 kg.

19. Multrys® is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate, and selenious acid) indicated in neonatal and pediatric patients weighing less than 10 kg

as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

20. Tralement® and Multrys®, as well as the use of Tralement® and Multrys® in accordance with their labels, are covered by one or more claims of the Patents-in-Suit.

21. ARI is the owner of the ’548 patent, which is entitled “Trace element compositions, methods of making and use” and was duly and legally issued on October 17, 2023. A copy of the ’548 patent is attached as Exhibit 1.

22. The ’548 patent has been listed in connection with Tralement® and Multrys® in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”).

23. As indicated in the Orange Book, the patent expiration date for the ’548 patent is July 1, 2041.

24. ARI is the owner of the ’022 patent, which is entitled “Trace element compositions, methods of making and use” and was duly and legally issued on May 7, 2024. A copy of the ’022 patent is attached as Exhibit 2.

25. As indicated in the Orange Book, the patent expiration date for the ’022 patent is July 1, 2041.

26. ARI is the owner of the ’565 patent, which is entitled “Trace element compositions, methods of making and use” and was duly and legally issued on June 4, 2024. A copy of the ’565 patent is attached as Exhibit 3.

27. As indicated in the Orange Book, the patent expiration date for the ’565 patent is July 1, 2041.

28. By letter dated June 14, 2024 ("the Notice Letter"), Gland Pharma notified ARI pursuant to the Federal Food, Drug, and Cosmetic Act that Gland Pharma had submitted to the FDA the ANDA with a Paragraph IV Certification to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products prior to the expiration of the Patents-in-Suit.

29. On information and belief, Gland Pharma submitted the ANDA to the FDA, which contained a Paragraph IV Certification asserting that the Patents-in-Suit will not be infringed by the manufacture, use, offer for sale, sale, or importation of the ANDA Products, or alternatively, that the Patents-in-Suit are invalid.

30. The Notice Letter asserted defenses of non-infringement for certain, but not all, claims of the Patents-in-Suit. The Notice Letter did not assert defenses of non-infringement for any claim of the '022 patent and did not assert defenses of non-infringement for claims 1–6, 9, and 12–58 of the '548 patent.

31. Since ARI received the Notice Letter and filed its initial Complaint against Gland Pharma (ECF No. 1), the '956 and '957 patents has been listed in connection with Tralement® and Multrys® in the Orange Book.

32. ARI is the owner of the '956 patent, which is entitled "Trace element compositions, methods of making and use" and was duly and legally issued on November 26, 2024. A copy of the '956 patent is attached as Exhibit 4.

33. As indicated in the Orange Book, the patent expiration date for the '956 patent is July 1, 2041.

34. ARI is the owner of the ’957 patent, which is entitled “Trace element compositions, methods of making and use” and was duly and legally issued on November 26, 2024. A copy of the ’957 patent is attached as Exhibit 5.

35. As indicated in the Orange Book, the patent expiration date for the ’957 patent is July 1, 2041.

36. On information and belief, the ANDA Products are generic versions of Tralement® (trace elements injection 4*, USP) and Multrys® (trace elements injection 4*, USP), as their reference listed drugs, containing the same or equivalent ingredients in the same or equivalent amounts.

37. In the Notice Letter, Gland Pharma disclosed that the ANDA Products are (1) a single-dose, 1 mL generic version of Tralement® containing 3 mg of zinc, 0.3 mg of copper, 55 mcg of manganese, and 60 mcg of selenium; and (2) a single-dose, 1 mL generic version of Multrys® containing 1000 mcg of zinc, 60 mcg of copper, 3 mcg of manganese, and 6 mcg of selenium.

38. On information and belief, the ANDA Products contain zinc, copper, manganese, and selenium in the same or equivalent amounts as Tralement® and Multrys®, respectively.

39. On information and belief, the ANDA Products will feature the same or equivalent chemical and therapeutic properties as Tralement® and Multrys®.

COUNT I: INFRINGEMENT OF THE ’548 PATENT

40. ARI realleges paragraphs 1–39 as if fully set forth herein.

41. Gland Pharma’s submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the ’548

patent, constitutes direct and indirect infringement of the ’548 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

42. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Gland Pharma or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the ’548 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Gland Pharma’s specific intent and encouragement, and will be conduct that Gland Pharma knows or should know will occur. On information and belief, Gland Pharma will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI’s rights under the ’548 patent.

43. On information and belief, Gland Pharma’s commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and/or contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the ’548 patent, either literally or under the doctrine of equivalents. On information and belief, Gland Pharma intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Gland Pharma knows that the ANDA Products are especially made or adapted for use in infringing the ’548 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

44. ARI will be irreparably harmed if Gland Pharma is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '548 patent, or any later expiration of exclusivity for the '548 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

45. Gland Pharma has had knowledge of the '548 patent since at least the date Gland Pharma submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

46. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF THE '022 PATENT

47. ARI realleges paragraphs 1–46 as if fully set forth herein.

48. Gland Pharma's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the '022 patent, constitutes infringement of the '022 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

49. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Gland Pharma or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which

will constitute direct infringement by patients and/or medical practitioners of one or more claims of the ’022 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Gland Pharma’s specific intent and encouragement, and will be conduct that Gland Pharma knows or should know will occur. On information and belief, Gland Pharma will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI’s rights under the ’022 patent.

50. On information and belief, Gland Pharma’s commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute induced infringement under 35 U.S.C. § 271(b) and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the ’022 patent, either literally or under the doctrine of equivalents. On information and belief, Gland Pharma intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Gland Pharma knows that the ANDA Products are especially made or adapted for use in infringing the ’022 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

51. ARI will be irreparably harmed if Gland Pharma is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the ’022 patent, or any later expiration of exclusivity for the ’022 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

52. Gland Pharma has had knowledge of the ’022 patent since at least the date Gland Pharma submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

53. This case is “exceptional,” and ARI is entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT III: INFRINGEMENT OF THE ’565 PATENT

54. ARI realleges paragraphs 1–54 as if fully set forth herein.

55. Gland Pharma’s submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the ’565 patent, constitutes direct and indirect infringement of the ’565 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

56. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Gland Pharma or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the ’565 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Gland Pharma’s specific intent and encouragement, and will be conduct that Gland Pharma knows or should know will occur. On information and belief, Gland Pharma will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI’s rights under the ’565 patent.

57. On information and belief, Gland Pharma's commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '565 patent, either literally or under the doctrine of equivalents. On information and belief, Gland Pharma intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Gland Pharma knows that the ANDA Products are especially made or adapted for use in infringing the '565 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

58. ARI will be irreparably harmed if Gland Pharma is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '565 patent, or any later expiration of exclusivity for the '565 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

59. Gland Pharma has had knowledge of the '565 patent since at least the date Gland Pharma submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

60. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IV: INFRINGEMENT OF THE '956 PATENT

61. ARI realleges paragraphs 1–60 as if fully set forth herein.

62. Gland Pharma's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product in or into the United States, prior to the expiration of the '956 patent, constitutes direct and indirect infringement of the '956 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

63. On information and belief, the ANDA Product, if the ANDA is approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Gland Pharma or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '956 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Product will occur with Gland Pharma's specific intent and encouragement, and will be conduct that Gland Pharma knows or should know will occur. On information and belief, Gland Pharma will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '956 patent.

64. On information and belief, Gland Pharma's manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '956 patent, either literally or under the doctrine of equivalents. On information and belief, Gland Pharma intends that the ANDA Product be used by patients and

medical professionals. Also, on information and belief, Gland Pharma knows that the ANDA Product is especially made or adapted for use in infringing the ’956 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

65. ARI will be irreparably harmed if Gland Pharma is permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the ’956 patent, or any later expiration of exclusivity for the ’956 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

66. This case is “exceptional,” and ARI is entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT V: INFRINGEMENT OF THE ’957 PATENT

67. ARI realleges paragraphs 1–66 as if fully set forth herein.

68. Gland Pharma’s submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product in or into the United States, prior to the expiration of the ’957 patent, constitutes direct and indirect infringement of the ’957 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

69. On information and belief, the ANDA Product, if the ANDA is approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Gland Pharma or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners

of one or more claims of the ’957 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Product will occur with Gland Pharma’s specific intent and encouragement, and will be conduct that Gland Pharma knows or should know will occur. On information and belief, Gland Pharma will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI’s rights under the ’957 patent.

70. On information and belief, Gland Pharma’s manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the ’957 patent, either literally or under the doctrine of equivalents. On information and belief, Gland Pharma intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Gland Pharma knows that the ANDA Product is especially made or adapted for use in infringing the ’957 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

71. ARI will be irreparably harmed if Gland Pharma is permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the ’957 patent, or any later expiration of exclusivity for the ’957 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

72. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, ARI prays that this Court grant the following relief:

(a) A judgment under 35 U.S.C. § 271(e)(2)(A) that Gland Pharma has infringed at least one claim of the Patents-in-Suit through Gland Pharma's submission of the ANDA with a Paragraph IV Certification to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States the ANDA Products before the expiration of the Patents-in-Suit;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Gland Pharma's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of the ANDA Products before the expiration of the Patents-in-Suit will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the Patents-in-Suit;

(c) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the ANDA, shall not be earlier than the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which ARI is or becomes entitled;

(d) The entry of a permanent and/or preliminary injunction enjoining Gland Pharma, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, having made, using, offering to sell, selling, marketing, distributing, and importing in or into the United States the ANDA Products, or any product that infringes any of the Patents-in-Suit, or inducing or contributing to the infringement of any of the Patents-in-Suit until after the expiration date of the Patents-in-Suit, including any extension and/or additional periods

of exclusivity to which ARI is or becomes entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(e) The entry of a permanent and/or preliminary injunction enjoining Gland Pharma, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the Patents-in-Suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(f) Damages or other monetary relief to ARI if Gland Pharma engages in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of the ANDA Products prior to the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which ARI is or becomes entitled;

(g) A finding that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding ARI its attorneys' fees incurred in this action; and

(h) Such further relief as this Court deems proper and just.

Dated: January 9, 2025

By: s/ Charles H. Chevalier

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American Regent, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on January 9, 2025, copies of the foregoing AMENDED COMPLAINT FOR PATENT INFRINGEMENT TO GLAND PHARMA and all exhibits were caused to be served on counsel of record via ECF and email.

Date: January 9, 2025

s/ Charles H. Chevalier
Charles H. Chevalier